### **PATENT COOPERATION TREATY**

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### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C-396	FOR FURTHER A	CTION	See Form PCT/IPEA/416				
International application No. PCT/EP2004/052894	International filing date 09.11.2004	(day/month/year)	Priority date (day/month/year) 11.11.2003				
International Patent Classification (IPC) or national classification and IPC C07C231/02, C07C231/24, C07C233/08							
Applicant ZAMBON GROUP S.P.A.							
This report is the international prei Authority under Article 35 and tran	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.						
2. This REPORT consists of a total of	of 4 sheets, including t	his cover sheet.					
3. This report is also accompanied by	y ANNEXES, comprisi	ng:					
a. $\square$ sent to the applicant and to	the International Bure	au) a total of sheets.	as follows:				
sheets of the description and/or sheets containing							
□ sheets which supersed beyond the disclosure Supplemental Box.	le earlier sheets, but w in the international app	hich this Authority con dication as filed, as ind	siders contain an amendment that goes licated in item 4 of Box No. I and the				
b. (sent to the International Busequence listing and/or table Box Relating to Sequence	les related thereto. in c	omputer readable forn	per of electronic carrier(s)) , containing a n only, as indicated in the Supplemental a Instructions).				
4. This report contains indications rel	ating to the following it	ems:					
Box No. I Basis of the opin	ion						
☐ Box No. II Priority		•					
☐ Box No. III Non-establishme	ent of opinion with rega	rd to novelty, inventive	step and industrial applicability				
Box No. IV Lack of unity of i	nvention						
applicability; cita	tions and explanations	2) with regard to novelt supporting such state	y, inventive step or industrial ment				
Box No. VI Certain documer							
Box No. VII Certain defects in			i				
☐ Box No. VIII Certain observat	ions on the internation	al application					
Date of submission of the demand		Date of completion of the	nis report				
25.05.2005		05.10.2005					
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 52365 Fax: +49 89 2399 - 4465		Authorized Officer Goetz, G Telephone No. +49 89 2	2399-				

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/EP2004/052894

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_	Вс	x No. I Basis of the report				
1	. Wi file	With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.				
		This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:  ☐ international search (under Rules 12.3 and 23.1(b)) ☐ publication of the international application (under Rule 12.4) ☐ international preliminary examination (under Rules 55.2 and/or 55.3)				
2. With regard to the <b>elements*</b> of the international application, this report is based on (replacement sheets whave been furnished to the receiving Office in response to an invitation under Article 14 are referred to in the report as "originally filed" and are not annexed to this report):						
	Des	cription, Pages				
	1-7	as originally filed				
	Cla	ims, Numbers				
	1-2	as originally filed				
		a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing				
3.		The amendments have resulted in the cancellation of:  ☐ the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/figs ☐ the sequence listing (specify): ☐ any table(s) related to sequence listing (specify):				
4.	Cup	This report has been established as if (some of) the amendments annexed to this report and listed below not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the plemental Box (Rule 70.2(c)).  the description, pages the claims, Nos.  the drawings, sheets/figs the sequence listing (specify):  any table(s) related to sequence listing (specify):				
	*	If item 4 applies, some or all of these sheets may be marked "superseded "				

#### INTERNATIONAL PRELIMINARY REPORT **ON PATENTABILITY**

International application No. PCT/EP2004/052894

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

2-14, 16-25

No: Claims

1,15

Inventive step (IS)

Yes: Claims No:

1-25

Industrial applicability (IA)

Yes: Claims

Claims

1-25

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

- D1: DATABASE WPI Section Ch, Week 200155 Derwent Publications Ltd., London, GB; Class B05, AN 2001-497525 XP002325720 & CN 1 297 885 A (HANGZHOU SHOUXIN FINE CHEM CO LTD) 6 June 2001 (2001-06-06)
- D2: WO 02/34709 A (ZAMBON GROUP S.P.A; CANNATA, VINCENZO; NICOLI, ANDREA; CORCELLA, FRANC) 2 May 2002 (2002-05-02)
- D3: WO 03/002517 A (BROMINE COMPOUNDS LTD; OREN, JACOB) 9 January 2003 (2003-01-09)
- 1. D1 discloses a process for preparing 1,1-cyclohexanediacetic acid monoamide by amination of 1,1-cyclohexanediacetic acid anhydride at a temperature of 30-110°C. Present claims 1 and 15 seek to distinguish the claimed subject matter from the disclosure of D1 only in terms of the upper limit required to be "lower than 30°C". It is, however, general knowledge that every experimental measurement in quantitative analytical chemistry as well as any result of any physical measurement cannot be dissociated from the margin of uncertainty attached to the measurement. Since the claimed process seeks to distinguish from the disclosure of D1 only in terms of the upper limit required to be "lower" than the value given in D1, the claimed subject matter is still not distinguishable from the prior art disclosed in D1. The subject matter of present claims 1 and 15 is thus considered not to be novel over the disclosure of D1 (PCT Article 33.2).
- 2. D3 discloses the same type of reaction where the reaction temperature is below 20°C (thus within the claimed range), however, the NH<sub>3</sub>/anhydride molar ratio is higher, namely 5 to 10 (see D3: claims 1 to 3).

  Having regard to the disclosure of D1 as well as the disclosure of D3 the subject matter of present claims 1 to 25 is not regarded to be based on an inventive step since it appears that the temperature as well as the molar NH<sub>3</sub>/anhydride ratio can be varied within a great range without being detrimental to the reaction. The skilled person can see from both documents that variation of these two parameters can be done. In addition no unexpected effect has been demonstrated which could be a hint for the presence of an inventive step.

The subject matter of present claims 1 to 25 is thus considered not to be based on an inventive step over the disclosure of D1 and D3 (PCT Article 33.2).